

Revised Summary for S-357

510(k)
Summary (Revision 1)

OCT 15 1996

K962684

Del Medical Systems feels the S-357 Video Imaging System is substantially equivalent to the many marketed devices already in commercial distribution. The legally marketed devices already in commercial distribution are: Circon/ACMI, Storz, Stryker, Smith & Nephew and Olympus, just to name a few.

The design of the S-357 is virtually identical to the comparative device as listed in the above paragraph.. Since the design is comparable, technology virtually identical, the specifications very similar, and the intended use the same as those above listed devices, DMS feels that these minor differences have no impact on the safe use and/or effectiveness of the device.

For information purposes and completeness, Del Medical Systems has also incorporated other legally marketed devices in this filing to illustrate the wide, general use of similar other devices. This wide use has led to the safe use of the device in many practitioner's hands.